DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
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Silver Spring, MD 20993-0002

October 28, 2014

Biological Signal Processing, Ltd.
% Ahava Stein
A. Stein Regulatory Affairs Consulting Ltd.
20 Hata' As Str., Suite 102
Kfar Saba, 44425 Israel

Re: K140020
Trade/Device Name: HyperQ Rest System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph; Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: DPS, MWI
Dated: August 3, 2014
Received: August 8, 2014

Dear Ahava Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140020

Device Name
HyperQ Rest

Indications for Use *(Describe)*
The BSP HyperQ™ Rest System is intended to be used during rest ECG tests, using the analysis of high frequency components present within the central portion of the QRS complex (HF-QRS). The device outputs a reduced amplitude zone (RAZ) value for the physician to interpret (based on reported clinical study results). The device is indicated for use in the ECG interpretation of patients with acute chest pain presenting to the Emergency Department, aged 18 years and above, as an additional adjunctive aid during initial patient presentation. The significance of the HF-QRS changes and interpretation of the HyperQ™ Rest analysis must be determined by a physician, based on the reported clinical study results presented in the device labeling.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

BSP HYPERQ™ ACS-100 SYSTEM

510(k) Number K140020

Applicant Name:

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Date Prepared: October 12, 2014

Trade Name: BSP HyperQ™ Rest System

Classification Name: CFR Classification section 870.2340; (Product code DPS)

Classification: Class II Medical Device

Predicate Device:

The BSP HyperQ™ Rest System is substantially equivalent to the following predicate devices.

Manufacturer	Device	510(k) No.
GE Medical Systems Information Technologies	MAC 800 Resting ECG Analysis System	K090212
BSP Ltd.	HyperQ™ AD-100 System	K102579

Device Description:

The HyperQ™ Rest System measures, processes, stores, and displays information derived from an electrocardiogram (ECG) with a high sampling rate (1000Hz). The device analyzes and records the High Frequency components of the QRS complex of standard ECG (HFQRS). The device displays the HFQRS to the user and also summarizes the analysis to generate an indication whether observed changes are within normal HyperQ range, or constitute significant HyperQ changes (Reduced Amplitude Zones, a.k.a RAZ); or represent a non-diagnostic test (unreadable). These findings are used as an aid in the clinical evaluation of acute chest pain on initial presentation to the Emergency Department.

Intended Use/Indication for Use:

The BSP HyperQ™ Rest System is intended to be used during rest ECG tests, using the analysis of high frequency components present within the central portion of the QRS complex (HF-QRS). The device outputs a reduced amplitude zone (RAZ) value for the physician to interpret (based on reported clinical study results). The device is indicated for use in the ECG interpretation of patients with acute chest pain presenting to the Emergency Department, aged 18 years and above, as an additional adjunctive aid during initial patient presentation. The significance of the HF-QRS changes and interpretation of the HyperQ™ Rest analysis must be determined by a physician, based on the reported clinical study results presented in the device labeling.

Performance Standards:

The BSP HyperQ™ Rest System is identical in hardware to the BSP HyperQ™ AD-100, which was cleared under K102579. The Rest therefore maintains compliance with the recognized consensus standards previously described for the AD-100 device.

Non-Clinical (Bench) Performance Data:

Not applicable.

Pre-Clinical (Animal Study) Performance Data:

Not Applicable

Clinical Performance Data:

The effectiveness of the BSP HyperQ™ Rest system was demonstrated in a clinical study. High frequency ECG signals were analyzed to obtain an automatic interpretation indicating significant HyperQ changes or changes within normal range for all tests that were readable. The analysis was based solely on the digital data from the ECG device and was compared to a gold standard diagnosis from the database.

Demographic data, ECG recordings and gold-standard diagnostics were used as a source for validating the diagnostic accuracy of the system. Results demonstrated that the device can be used as an aid in the identification of Reduced Amplitude Zones (RAZ) values in patients presenting with acute chest pain to an Emergency Department, aged 18 years and above.

Technological Characteristics:

The technology of the BSP devices involves analysis of High Frequency QRS (HFQRS) components of the ECG signal (HFQRS), made possible by the high frequency sampling rate. The high frequency range is represented by the HyperQ™ signal. The morphology of the HyperQ envelope is examined for existence of reduced amplitude zones (RAZ) and High Frequency Morphological Indexes (HFMI) are extracted. The level of RAZ of all 12 leads is quantified by the HFMI, providing the user with a quantitative value.

Substantial Equivalence:

The indications for use and technological characteristics of the BSP HyperQ™ Rest device are substantially equivalent to the indications for use and technological characteristics of the Predicate GE MAC 800 Resting ECG Analysis System and the HyperQ AD-100 System.

The primary difference between the HyperQ AD-100 and the HyperQ Rest is in the indication for use for rest ECG analysis from the acquired ECG. The predicate device GE MAC 800 Resting ECG Analysis System (K090212) is specifically indicated for

rest ECG Testing. Based upon the validation results, BSP believes this change does not raise additional safety or efficacy concerns.

The design and components in the BSP HyperQ™ Rest system, including the hardware and software, are similar to the design and components found in the predicate HyperQ™ AD-100 System. The algorithm was modified to allow for analysis of rest ECG signals. The minor differences in the software user interface are insignificant and do not influence the safety or efficacy of the device. The performance specifications (including display of High Frequency QRS signals, and morphological assessment of them) of the BSP HyperQ™ Rest system are substantially equivalent to those in the HyperQ™ AD-100 System. There are no patient contact materials. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the new BSP HyperQ™ Rest System is identical in its hardware to the HyperQ™ AD-100 System. The AD-100 system underwent performance testing, including electrical and mechanical safety testing according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2. These were provided in the original 510(k) submission of the HyperQ™ AD-100 System, and are not repeated in this submission. As the software algorithm was modified, software validation testing was performed. The results of the software validation tests demonstrated that the device meets its specifications, which are similar to those of the predicate device. These performance tests demonstrated that the minor differences in the device specifications meet the system requirements and do not raise new safety or effectiveness concerns. Furthermore, the results of the clinical study performed demonstrate that the device provides an effective tool as an aid in the diagnostic process of acute chest pain in patients aged 18 years and above, for the identification of RAZ in the ECG signal.

Conclusions:
Based on the performance testing and comparison to predicate devices, the BSP HyperQ™ Rest System is substantially equivalent to the predicate devices.